PHARMACY EXAMINING BOARD AUGUST 11, 2004 – MINUTES

PRESENT: Cynthia Benning, R.Ph.; Michael Bettiga, R.Ph.; John Bohlman, R.Ph.;

Georgia Forbes; Fredric Moskol, R.Ph.; Charlotte Rasmussen; and Susan

Sutter, R.Ph.

STAFF PRESENT: Tom Ryan, Bureau Director; William Black, DRL Board Counsel; Kevin

Murphy, Bureau Assistant; DOE Staff

GUESTS: Eric Schulenburg, Attorney for Michael Hiller; Michael Hiller, R.Ph.;

Susan Hanosh, Walgreens; Maribeth Pauli, DPH-4; John Lascewski; Lori Jensen, DPH-4; Jeannette Roberts, Ph.D, UW School of Pharmacy; Justin Pacult, PSW; Shelly Raebel, Purdue Pharmacy; Doug Engelbert, DHFS; Ryan Bender, Student-DHFS intern; Rich Verschay, R.Ph., Appointed Board Member; Steve Rough, R.Ph., UW Hospital; Robin Sheldan, Quad Med; Dr. Amy Helwig, Quad Med; Patrick Ross, R.Ph., Quad Med; Michelle Frazier, Von Briesen & Roeper; Mary Krueger, Ministry Health; Kathy Tarcon, Diagnostic & Surgical Services Center; Dick Cook, St. Joseph's Hospital, Director of Pharmacy; Lisa Gingerich, Von Briesen &

Roeper; Mary Krueger, SDC Healthcare.

CALL TO ORDER

Chair Michael Bettiga called the meeting to order at 9:00 a.m.

WELCOME NEW APPOINTMENT AND MOTION TO INVITE NEW APPOINTMENT INTO CLOSED SESSION

MOTION: John Bohlman moved, seconded by Charlotte Rasmussen, to invite the

new Board appointment, Rich Verschay, into closed session. Motion

carried unanimously.

APPROVAL OF AGENDA

The Bureau Director noted the additions of a variance request by St. Clare's Hospital between items I and J, and the addition of the 14 Airgas manufacturer/distributor applications between items F and G.

MOTION: Cynthia Benning moved, seconded by Susan Sutter, to approve the agenda

as amended. Motion carried unanimously.

APPROVAL OF MINUTES OF JUNE 24 AND JULY 13, 2004

Changes to the June 24, 2004 minutes:

- The Board decided to strike from "There was information..." to the end of the paragraph in the first paragraph of page 7.
- The Board also decided to put a heading on their discussion of the emergency situation at Aurora Pharmacy in Montello, WI.
- Under Internship Requirements, change "re-enact" to "reinitiate".

MOTION: Susan Sutter moved, seconded by John Bohlman, to approve the June 24, 2004 minutes as amended. Motion carried unanimously.

Changes to the July 13, 2004 minutes:

- On page 19, under prescription monitoring, change "mandated" to "implemented".
- Also on page 19, strike the sentence beginning with "Ms. Sutter questioned..." and replace it with "Ms. Sutter urged the gathering of outside input from other state officials to such a program before pursuing legislation."
- On page 18, strike the first sentence of the final paragraph. Begin the second sentence with "Ms. Benning and Mr. Bohlman said that…"
- Under Consultation Exam Format, strike the last sentence of the first paragraph.

MOTION: Cynthia Benning moved, seconded by Susan Sutter, to approve the July 13, 2004 minutes as amended. Motion carried unanimously.

PRESENTATION OF PROPOSED STIPULATIONS

DOE Attorney Jim Polewski presented the proposed stipulation, final decision and order in the disciplinary proceedings against Michael Hiller, R.Ph.

ADMINISTRATIVE REPORT

The Bureau Director discussed the new appointments, Pamela Phillips and Rich Verschay, and the upcoming Board Member Workshop.

MOTION: Charlotte Rasmussen moved, seconded by Susan Sutter, to appoint Cindy Benning as the alternate to Susan Sutter as the Licensing Liaison. Motion carried unanimously.

DRL Board Counsel volunteered to draft guidelines for the licensing liaison to handle minor variance requests.

MOTION: Cynthia Benning moved, seconded by Georgina Forbes, to amend the previous motion. The Board Chair, Michael Bettiga, shall serve as the second alternate to the licensing liaison. Motion carried unanimously.

MOTION: Cynthia Benning moved, seconded by John Bohlman, to add an

examination duty to the licensing liaison position. This duty is limited to Wisconsin Administrative Code § 4.05 on retakes of exams. Motion

carried unanimously.

MOTION: Susan Sutter moved, seconded by Charlotte Rasmussen, to reappoint John

Bohlman for another 6 month term as the DOE monitoring liaison to the Board. The terms of this duty will be identical to those spelled out in the

February 11, 2004 motion. Motion carried unanimously.

Mr. Bohlman commented that the high quality of work done in DOE monitoring is largely attributable to Linda Nichols, a member of the DRL Staff who was recently slotted in the monitoring position. Mr. Bohlman commended Ms. Nichols for her excellent work.

Dave O'Connell introduced to the Board Eric Calisto, J.D., the new DOE Division Administrator. The Bureau Director added information with respect to Mr. Calisto's background as an attorney in service to the people of Wisconsin.

EXAMINATIONS WORK – DARWIN TICHENOR, DRL OFFICE OF EDUCATION AND EXAMINATIONS

The Chair inquired about the status of an NABP survey on the procedures of other states with respect to practice exams. The Board agreed to discuss this item at the October meeting.

APPLICATION REVIEW (DISTRIBUTOR) – INTERVET, INC. – KIM J. LEWIS – MILLSBORO, DE

The Board took no action on this matter due to a lack of information on prior Intervet disciplines in other states. (See page 6 for Board action)

APPLICATION REVIEW (DISTRIBUTOR) – SPARHAWK LABORATORIES, INC. – LINDA FLETCHER – LENEXA, KS

MOTION: Cynthia Benning moved, seconded by John Bohlman, to take no action on

the Sparhawk matter, but to follow up once more information on prior

violations is provided. Motion carried unanimously.

The Sparhawk matter will be referred to DOE for further investigation.

APPLICATION REVIEW (DISTRIBUTOR) – ALK-ABELLO, INC. – P. ALDAHONDO – PORT WASHINGTON, NY

MOTION: Cynthia Benning moved, seconded by John Bohlman, to take no action on

the ALK-Albello matter until more information on prior violations is

provided.

The ALK application will be referred to DOE for investigation.

APPLICATION REVIEW (DISTRIBUTOR/MANUFACTURER) – AIRGAS NORTH CENTRAL – CINDY LUSK – WEST CHICAGO, IL

MOTION: Susan Sutter moved, seconded by John Bohlman, to release Airgas distributors licenses to the following applications (listed):

- # 205767 (Green Bay)
- # 205773 (Marinette)
- # 205769 (Manitowoc)
- # 205764 (Fond du Lac)
- # 205763 (Appleton)
- # 205777 (Schofield)
- # 205778 (St. Paul, MN)
- #205776 (New Berlin)
- # 205768 (Madison)

Manufacturers licenses shall be granted to the following applications (listed):

- # 205760 (Marinette)
- # 205762 (Madison)
- # 205759 (New Berlin)
- # 206949 (Dubuque, IA)
- # 205761 (Schofield)

Motion carried unanimously.

Michael Bettiga then introduced Jeanette Roberts, Dean of the UW School of Pharmacy

VARIANCE REQUEST – SHOPKO STORES, INC. – KEN WALKER, R.PH. – GREEN BAY, WI

Michael Bettiga left the meeting room for discussion and voting.

MOTION:

Cynthia Benning moved, seconded by Georgina Forbes, to state that no variance is needed under § 7.05. For non-controlled prescription drugs, no variance is needed under the circumstances. For controlled substances, if Shopko does not have a common central processing unit, Shopko cannot perform electronic transfer more than one time, as stated under § 7.05 (5). Motion carried.

VARIANCE REQUEST – UNIVERSITY OF WISCONSIN HOSPITAL – STEVE ROUGH, R.PH. – MADISON, WI

Steve Rough appeared before and answered questions from the Board.

MOTION: John Bohlman moved, seconded by Susan Sutter, to grant the variance

request in the matter of "Tech Check Tech" under the condition that UW Hospital will submit a documented report every six months and file an

annual request for renewal. Motion carried unanimously.

The Board agreed to have the variance expire in July of 2005, and to have the variance renewable in the month of the next available Board Meeting after July.

VARIANCE AMENDMENT REQUEST – QUAD MED INC. – MICHELLE FRAZIER – MILWAUKEE, WI.

Ms. Frazier, Von Briesen & Roeper, appeared on behalf of Quad Med requesting an amendment to the 1997 shuttling variance. She answered questions from the Board.

MOTION: Fredric Moskol moved, seconded by Cynthia Benning, to grant the

variance request as amended. The Board will require semi-annual reports to be completed by January 1 and July 1 of each year. Susan Sutter

abstained from discussion and voting. Motion carried.

APPLICATION REVIEW – STAFF DEVELOPMENT CORPORATION (SDC) HEALTHCARE – MARY KRUEGER – WAUWATOSA, WI

Ms. Krueger answered questions from the Board regarding SDC procedures.

MOTION: Susan Sutter moved, seconded by Cynthia Benning, to grant a variance for

the size of the pharmacy, under the condition that only drugs whose route of administration is nebulization can be dispensed from the Pharmacy. SDC must submit a list of its formulary to DRL Board Counsel. If the

formulary changes, SDC must notify the Board. Motion carried

unanimously.

VARIANCE REQUEST - ST. CLARE'S HOSPITAL OF WESTON, INC. – MARSHFIELD CLINIC – LISA GINGERICH – MADISON, WI

Kathy Tarcon of Diagnostic and Surgical Services Center, Mary Krueger of Ministry Health, Dick Cook of St. Joseph's Hospital, and Lisa Gingerich of Von Briesen & Roeper made a brief presentation to and answered questions from the Board. The Board discussed the definition of a hospital, questions surrounding the myriad legal possibilities and implications related to automated dispensing machines, and issues surrounding access by citizens of this state in remote locales. After some lengthy discussion, the Board concluded that no variance was needed.

LATE RENEWALS/PAST BOARD PROCEDURES – DISCUSSION

The Board reviewed past meeting minutes on late renewals.

PRACTICE QUESTION – MARY WAGNER (NACDS) – DEA FORM 222 COMPLIANCE QUESTION

DRL Board Counsel reviewed a 3 page document he prepared, summarizing the proposed DEA rule regarding the use of a "digital certificate" in place of the current paper form 222. The Board decided to take no action on the matter, at this time. Bill Black agreed to draft a letter to Mary Wagner explaining that NACDS is in compliance with current Board rules.

WOMEN'S INTERNATIONAL PHARMACY (WIP) – REQUEST FOR MODIFICATION OF ORDER– HOWARD HOFFMAN, ESQ.

Mr. Hoffman gave a lengthy background of the WIP matter and presented a set of arguments to the Board.

MOTION: Susan Sutter moved, seconded by John Bohlman, to appoint Cindy

Benning, John Bohlman, and Charlotte Rasmussen to a workgroup to review the matter. DRL Counsel Bill Black will assist the workgroup. The workgroup will present its findings at the October meeting. Motion

carried unanimously.

At 12:25 p.m., the Board took a 35 minute break for lunch. The meeting resumed at 1:10.

APPLICATION REVIEW (DISTRIBUTOR) – INTERVET, INC. – KIM J. LEWIS – MILLSBORO, DE

After reviewing additional information in the Intervet, Inc. matter, the Board took the following action:

MOTION: Susan Sutter moved, seconded by Cynthia Benning, to grant a distributor's

license to Intervet, Inc. Motion carried unanimously.

LICENSING LIAISON REPORT – SUE SUTTER

Ms. Sutter noted that since July 1, the Board has licensed 112 pharmacists, 20 distributors, 10 pharmacies, and zero manufacturers.

USP REPORT – CINDY BENNING

Ms. Benning noted that the USP-subgroup meets again in October, and that any issues arising from this meeting can be discussed in January. Much is unsettled. The Board agreed to explore the possibility of inviting Judy Thompson to share her expertise on this item in January.

WILLIAM HUBBARD, JULY 22, 2004 DHHS FDA LETTER TO GOVERNOR

The Board held a brief discussion on this item.

SUMMARY REPORTS ON PENDING COURT CASES, DISCIPLINARY CASES, ADMINISTRATIVE RULES AND LEGISLATION, INCLUDING:

Wis. Admin. Code PHAR § 7.04 – review latest edits for Clearinghouse review

DRL Board Counsel reviewed his latest edits. The Board offered additional improvements to the working draft. The discussion then turned to return policies, and whether pharmacies can legally put back on the shelf over-the-counter items returned by customers. DRL Board Counsel stated that it is his view that if the returned item was not damaged or tampered with, pharmacies could legally re-sell the item.

Returning to the discussion of § 7.04, DRL Board Counsel agreed to continue drafting, and the issue will be discussed at the October meeting.

DATCP PILL COUNT INSPECTIONS – STATUS – MICHAEL BETTIGA

The Board discussed the ongoing random pill count inspections, and questioned the agency's authority to perform these checks. DRL Board Counsel noted that the Pharmacy Examining Board has no jurisdiction in this matter. The Board questioned the rationale behind the checks, noting that it would be more sensible to check for problems with automatic counting machines per se rather than for episodes of fraud in sting fashion. Mr. Bettiga stated he would speak with the Secretary on this matter.

INFORMATIONAL ITEMS

Noted.

SCREENING REPORT

John Bohlman discussed Pharmacy break-ins, and possible prevention strategies to guard against them. Mr. Bohlman also discussed the possibility of working with DOE to create a list of strategies to limit the quantities of drugs stolen, if such a break-in were to occur.

CLOSED SESSION

MOTION:

Sue Sutter moved, seconded by Charlotte Rasmussen, to CONVENE TO CLOSED SESSION to deliberate on case(s) following hearing (Wis. Stat. § 19.85 (1) (a)); consider closing disciplinary investigation(s) with administrative warning(s) (Wis. Stat. § 19.85 (1) (b) and 440.205); to consider individual histories or disciplinary data (Wis. Stat. § 19.85 (1) (f)); and to confer with legal counsel (Wis. Stat. § 19.85 (1) (g). Motion carried unanimously in a roll call vote.

The Board convened into closed session at 2:25 p.m.

RECONVENE INTO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION

MOTION: Charlotte Rasmussen moved, seconded by Cynthia Benning, to reconvene

into open session at 3:20 p.m. Motion carried unanimously.

APPLICATION REVIEW - JANE WEEKS

MOTION: Cynthia Benning moved, seconded by John Bohlman, to require Jane

Weeks to take the counseling exam. DRL Staff will notify Ms. Weeks of

this requirement. Motion carried unanimously.

CASE CLOSING - 03 PHM 083

MOTION: Susan Sutter moved, seconded by John Bohlman, to close case 03 PHM

083 for no violation. Motion carried unanimously.

DELIBERATION OF PROPOSED STIPULATION, FINAL DECISION AND ORDER IN THE DISCIPLINARY PROCEEDINGS AGAINST MICHAEL HILLER, R.PH. – COTTAGE GROVE, WI – CASE ADVISOR – JOHN BOHLMAN

MOTION: Cynthia Benning moved, seconded by Charlotte Rasmussen, to adopt the

stipulation, final decision and order in the disciplinary proceedings against

Michael Hiller. Motion carried unanimously.

MOTION: Susan Sutter moved, seconded by Charlotte Rasmussen, to grant a three

month stay in the matter of Michael Hiller. Motion carried unanimously.

DELIBERATION OF PROPOSED STIPULATION, FINAL DECISION AND ORDER IN THE DISCIPLINARY PROCEEDINGS AGAINST ROBERT BOGAUDO, R.PH. – VULCAN, MI – CASE ADVISOR – SUE SUTTER

MOTION: Cynthia Benning moved, seconded by John Bohlman, to adopt the

stipulation, final decision and order in the disciplinary proceedings against

Robert Bogaudo. Motion carried unanimously.

DOE MONITORING:

MARK ANDERSON, R.PH. – REQUEST FOR 3 MONTH STAY OF SUSPENSION WITH MODIFICATIONS

MOTION: John Bohlman moved, seconded by Susan Sutter, to grant the three month

stay of suspension but to deny modifications in the matter of Mark

Anderson. Motion carried unanimously.

ROBERT GUZZETTA, R.PH. – REQUEST FOR 3 MONTH STAY OF SUSPENSION WITH MODIFICATIONS

MOTION: Charlotte Rasmussen moved, seconded by John Bohlman, to grant a three

month stay of suspension with a pemoline drug test reduction, as long as Mr. Guzzetta is working in a nuclear pharmacy. The test will now be

required quarterly. Motion carried unanimously.

LANCE LUNDSTAD, R.PH. – REQUEST FOR 3 MONTH STAY OF SUSPENSION WITH MODIFICATIONS

MOTION: Susan Sutter moved, seconded by Georgina Forbes, to deny the request for

a 3 month stay of suspension in the matter of Lance Lundstad. Motion

carried unanimously.

JAMES MEYER, R.PH. – REQUEST FOR POSSIBLE VOLUNTARY SURRENDER

MOTION: Susan Sutter moved, seconded by Georgina Forbes, to impose an

indefinite suspension in the matter of James Meyer. Motion carried

unanimously.

JOHN SCHMITT, R.PH. – REQUEST FOR 3 MONTH STAY OF SUSPENSION WITH MODIFICATIONS

MOTION: Cynthia Benning moved, seconded by Charlotte Rasmussen, to grant a

three month stay of suspension but to deny modifications in the matter of John Schmitt. Michael Bettiga abstained from discussion and voting.

Motion carried.

GREGORY TECHE, R.PH. – REQUEST FOR 3 MONTH STAY OF SUSPENSION WITH MODIFICATIONS

MOTION: Cynthia Benning moved, seconded by Georgina Forbes, to grant the three

month stay of suspension but to deny modifications in the matter of

Gregory Teche. Motion carried unanimously.

EXAMINATION ISSUES

MOTION: Cynthia Benning moved, seconded by John Bohlman, to approve

examination scores. Motion carried unanimously.

ADJOURNMENT

MOTION: Susan Sutter moved, seconded by Cynthia Benning, to adjourn the

meeting at 3:34 p.m. Motion carried unanimously.

Next Meeting October 13, 2004